ASSESSING STROKE AND BLEEDING RISK IN ATRIAL FIBRILLATION

Consensus Statement on Appropriate Anticoagulant Use

EXECUTIVE SUMMARY

ASSESSING STROKE AND BLEEDING RISK IN ATRIAL FIBRILLATION:
Consensus Statement on Appropriate Anticoagulant Use
EXECUTIVE SUMMARY

Mark J. Alberts, MD; Mary Amatangelo, MS, ACNP-BC, CCRN; Kenneth A. Bauer, MD; Lynne T. Braun, PhD, CNP, FAHA; Henry I. Bussey, PharmD; A. John Camm, MD, QHP, FRCP, FACC, FESC, FMedSci, FHRS, CStJ; David Garcia, MD; Samuel Z. Goldhaber, MD; Jonathan L. Halperin, MD; Mellanie True Hills; Alan K. Jacobson, MD; Gregory Y.H. Lip, MD, FRCP, FESC, FACC; Edith A. Nutescu, PharmD, FCCP; Daniel E. Singer, MD; Albert L. Waldo, MD, FACC, FAHA, FHRS, FAACP

For full author information see end of text.

THE NUMBER OF AMERICANS AGE 65 OR OLDER is expected to increase 36% during this decade—reaching 54.8 million by 2020.[i] By 2030, there will be 72.1 million Americans aged 65 and older, and senior citizens will make up nearly 20% of the U.S. population.[i] This unprecedented and continuing aging of the population will be accompanied by a "Silver Tsunami" of age-related chronic diseases such as atrial fibrillation (AF), which increases in prevalence with age—approximately 2-3% of individuals in their 60s and 8-10% of those in their 80s have AF.[ii]

The risk of stroke, the most-feared consequence of AF, also increases with age, with individuals over the age of 85 facing almost double the stroke risk of those aged 75-84 (increasing from 2.8% to 4.7%).[iii] Based on demographic factors alone, annual healthcare expenditures related to stroke can be expected to increase to $140 billion by 2030.[iv] AF is also associated with an approximate doubling of the risk of all-cause mortality[v] and is a contributory cause of death for around 99,000 Americans each year.[vi]

Although anticoagulation is very effective at reducing AF-related strokes, a large percentage of patients do not receive stroke prophylaxis.[vii] Underuse of both ischemic stroke and bleeding risk assessment tools leads to underuse of anticoagulation for stroke prevention, and constitutes a major obstacle to optimal care. This failure to prescribe anticoagulation to high risk patients is driven by many factors, including misperceptions regarding the net clinical benefit of anticoagulant therapy, lack of incentives, time constraints, and lack of specificity as to contraindications. In addition, many healthcare providers over-estimate a patient's bleeding risk and under-estimate the risk of ischemic stroke. This is especially true among older adults, where the risk of bleeding events related to falls and mechanical frailty is often over-estimated.[ii]

The AF Optimal Treatment Task Force, led by the Alliance for Aging Research, convened an expert roundtable to discuss strategies for augmenting risk assessment and anticoagulation decision-making. The objective was to enhance the care and treatment of patients with AF, and reduce the stroke burden on the U.S. healthcare system. The roundtable participants arrived at a consensus on assessing risk and making decisions on antithrombotic therapy, identified needed health care professional and patient education materials and tools to support both risk assessment and implementation of new anticoagulation therapies, and highlighted areas requiring additional research.

Consensus Recommendations

The roundtable participants recommended a three-step approach to anticoagulation decision-making in patients with AF.

- First, a patient's **stroke risk** should be assessed using an established scoring tool (see Appendix A) and be reviewed and recorded in a chart or EMR no less than annually, as risk factors change. The most commonly used stroke risk scores are $CHADS_2$ and CHA_2DS_2-VASc. The latter modifies $CHADS_2$ to identify the lowest risk patients.
    - Those identified as intermediate or high risk should be put on an anticoagulant—warfarin or a direct thrombin inhibitor or a factor Xa inhibitor. Aspirin is not recommended for stroke prophylaxis in AF.
- Second, if the patient is at high enough risk to require anticoagulation therapy, the patient's **bleeding risk** should then be evaluated to estimate the net clinical benefit of anticoagulation, again using an available scoring tool as a starting point (see Appendix B).
    - Risk factors for ICH should be considered, including uncontrolled hypertension, concomitant antiplatelet therapy, small vessel disease and dementia. Also, while routine screening for cerebral amyloid angiopathy, leukokariosis, and ApoE genotype is not currently indicated, if previously diagnosed, these conditions should be considered.
    - For the majority of patients, the net benefit of stroke prophylaxis supersedes the "net harm" of serious bleeding events, even among older patients. Therefore, assessment of bleeding risk is not an opportunity to look for reasons not to anticoagulate, but rather an opportunity to address correctable risk factors for bleeding (examples include but are not limited to uncontrolled hypertension, anemia, renal impairment, labile INRs, concomitant prescription of aspirin or NSAIDs, ethanol abuse, reduced platelet count, and excessive fall risk). With the exception of the patient with an extremely increased risk of bleeding and a relatively low risk of stroke, those who are identified as having a high risk for bleeds should be monitored closely, and their correctable risk factors managed appropriately.

CONTINUED ON NEXT PAGE

- Third, the anticoagulation decision must reflect patient preferences and values. The patient must also understand the relative benefits and risks and be involved in the net value decision.

The roundtable participants also recommended that education and tools at the primary care and family practitioner levels be enhanced and disseminated. These could include stroke risk assessment tools in EMR systems, awareness activities and events at medical centers, educational initiatives by payers, pocket guides, and on-line resources.

Patient education materials, tools, and outreach must also be enhanced and promoted. Many patients are not aware that AF confers a five-fold increase in stroke risk. The U.S. healthcare system must raise awareness of AF and the associated stroke risk. Initiatives that prompt the patient to initiate a stroke prevention discussion with his or her PCP should be considered. Organizations should join forces to promote reputable on-line resources that provide accurate and objective healthcare information with a consistent message and voice.

While education of both patients and practitioners is critical, clear and consistent recommendations and incentives to comply are also necessary. With the treatment landscape rapidly changing, and treatment decisions becoming more complicated, different recommendations from various professional groups and health organizations complicates matters. A consensus promoted through these groups, guidelines, private and public payers, and other interested parties could increase anticoagulation rates.

The roundtable participants also agreed that priority should be given to collecting and analyzing real-world data on new anticoagulants to identify which patients are best suited for specific agents.

Author Affiliations

Mark J. Alberts, MD
Director, Stroke Program
Northwestern University Feinberg School of Medicine

Mary Amatangelo, MS, ACNP-BC, CCRN
Senior Stroke Researcher/Nurse Practitioner
MGH J. Philip Kistler Stroke Research Center

Kenneth A. Bauer, MD
Director, Thrombosis Clinical Research
Beth Israel Deaconess Medical Center

Lynne T. Braun, PhD, CNP, FAHA
Preventive Cardiology Center and Heart Center for Women
Rush College of Nursing

Henry I. Bussey, PharmD
Co-founder and Senior Editor
ClotCare.org Online Information Service

A. John Camm, MD, QHP, FRCP, FACC, FESC, FMedSci, FHRS, CStJ
Chairman, Dept. of Cardiac and Vascular Sciences
St. George's University of London

David Garcia, MD
Director, Anticoagulation Management Service
University of New Mexico School of Medicine

Samuel Z. Goldhaber, MD
Brigham and Women's Hospital
Harvard Medical School

Jonathan L. Halperin, MD
Mount Sinai Medical Center

Mellanie True Hills
CEO and Founder, StopAfib.org

Alan K. Jacobson, MD
Associate Chief of Staff, Research
Loma Linda School of Medicine

Gregory Y. H. Lip, MD, FRCP, FESC, FACC
University of Birmingham Center for Cardiovascular Sciences
City Hospital, Birmingham, United Kingdom

Edith A. Nutescu, PharmD, FCCP
Director, Antithrombosis Center
University of Illinois Hospital & Health Sciences System

Daniel E. Singer, MD
Chief, Clinical Epidemiology Unit
Massachusetts General Hospital

Albert L. Waldo, MD, FACC, FAHA, FHRS, FACCP
The Walter H. Pritchard Professor of Cardiology and Professor of Medicine
Case Western Reserve University

AFib Optimal Treatment Task Force

This consensus document was supported by the efforts of the AFib Optimal Treatment Task Force:

Alliance for Aging Research
The Anticoagulation Forum
Atrial Fibrillation Association
Clot Care
The Heart Rhythm Society
Mended Hearts
The Men's Health Network

National Forum for Heart Disease and Stroke Prevention
National Stroke Association
Preventive Cardiovascular Nurses Association
The Society for Women's Health Research
StopAfib.org

References

[i]Administration on Aging. *A profile of older Americans: 2011.* Washington, DC: US Department of Health and Human Services. 2011.

[ii] Go AS, EM Hylek, KA Phillips, et al. Prevalence of diagnosed atrial fibrillation in adults: national implications for rhythm management and stroke prevention. *JAMA*. 2001 May 9; 285(18): 2370-5.

[iii] Singer DE, Y Chang, M Fang, et al. The net clinical benefit of warfarin anticoagulation in atrial fibrillation. *Ann Intern Med*. 2009 Sep 1; 151(5):297-305.

[iv] Heidenreich PA, JG Trogdon, OA Khavjou, et al. Forecasting the future of cardiovascular disease in the United States: a policy statement from the American Heart Association. *Circulation*. 2011 Mar 1; 123(8): 933-44.

[v] Benjamin EJ, PA Wolf, RB D'Agostino, H Silbershatz, WB Kannel, D Levy. Impact of atrial fibrillation on the risk of death: The Framingham Heart Study. *Circulation.* 1998; 98:946-52.

[vi] Roger VL, AS Go, DM Lloyd-Jones, EJ Benjamin, JD Berry, WB Borden, DM Bravata, S Dai, ES Ford, CS Fox, HJ Fullerton, C Gillespie, SM Hailpern, JA Heit, VJ Howard, BM Kissela, SJ Kittner, DT Lackland, JH Lichtman, LD Lisabeth, DM Makuc, GM Marcus, A Marelli, DB Matchar, CS Moy, D Mozzaffarian, ME Mussolino, G Nichol, NP Paynter, EZ Soliman, PD Sorlie, N Sotoodehnia, TN Turan,SS Virani,ND Wong, D Woo, MB Turner. Heart disease and stroke statistics—2012 update. *Circulation*. 2012; 125:e12-e230.

[vii] Ogilvie IM, N Newton, SA Weiner, W Cowell, and GY Lip. Underuse of anticoagulants in atrial fibrillation: a systematic review. *Am J Med*. 2010 Jul 1; 638-45.